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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/606,342	06/25/2003	Guangyang Wang	TIBO-0003(TIP)	4013

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EXAMINER

OWENS, AMELIA A

ART UNIT PAPER NUMBER

1625

DATE MAILED: 12/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/606,342	Applicant(s) WANG ET AL.	
	Examiner Amelia A. Owens	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20,21,23-28 and 30-80 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 20,21,23-28,50-72 is/are allowed.
- 6) ☒ Claim(s) 30-49 and 75-80 is/are rejected.
- 7) ☒ Claim(s) 73-80 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. New claims 73-80 are added. Claims 20,21,23-28,30-80 are pending.

Claim Rejections - 35 USC § 112

2. The rejection of claims 20,21,30,33,38,43,54,66 under 35 USC 112 2nd paragraph is dropped as the claims have been amended and/or applicants remarks are persuasive.

3. Claims 20,21,23-28,30-80 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement and dropped. The state of the art is that combination retroviral regimens are known. See abstract of McGowan, et al, Prevention of perinatal HIV transmission during pregnancy, J. Antimicrobial Chemotherapy (200) 46, 657-6688. Support is found in the specification at page 7 line 39 thru page 8 line 30.

Support for the various forms is found at page 2 line 31 thru page 4 line 28. ^{if the specification} Further, the state of the art is that inhibiting retroviral replication and inhibiting a protease of a retrovirus are known. See Lori et al, Hydroxyurea : mechanisms of HIV-1 inhibition, PMID 10723506; Tomasselli et al, Targeting the HIV-protease in AIDS therapy; a current clinical perspective, Biochimica et Biophysica Acta 1477 (2000) 189-214.

In the absence of any evidence or apparent reason why the claimed compounds do not possess the disclosed utility, the allegation of utility in the specification must be accepted as correct. In re Kamal et al, 158 USPQ 320; Ex parte Krenzer, 199 USPQ 227. Thus, claims 20,21,23-28,50-72 are allowed.

4. Claims 30-37,75,76 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating, does not reasonably provide enablement for prevention. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The disclosure of the present invention is a kit for treating and preventing retroviral infections where the claimed formulation is administered to a subject. The term 'preventing' is not defined in the specification. Instead the term prophylaxis is used. The term prophylaxis has several definitions. There is nothing to imply that retroviral infections in general can be prevented. The state of the art is that in neonatal exposure and health care professional exposure,

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the likelihood of occurrence of retroviral infection or vertical transmission of retroviral infection may be reduced. See McGowan abstract. No data or evidence is present in the specification that the claimed formulation may prevent retroviral infections. Further, a broader definition of prevention would mean within the general population the formulation could prevent retroviral transmission. Applicant does not provide this definition or examples to support this definition.

Hence, the amount of guidance presented in the specification the absence of data indicating that retroviral infection do not occur when the claimed formulation is administered, and the state of the prior art indicating that treatment of retroviral infections is possible, all indicate that treatment, not prevention of retroviral infections is possible.

It is suggested that the language 'for preventing or treating retroviral infections,' be deleted. The kit may be used however the practitioner decides.

5. Claims 38-49,77-80 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are directed to a method of treating an infection associated with a retrovirus in a mammal. It is not clear from the disclosure whether the infection is the retrovirus per se or some other infection. See page 7 lines 18-27. It is the examiner's position that chronic CNS diseases are not infections. It is suggested the claim read --a method of treating a retrovirus infection in a mammal---.

Duplicate Claims

6. Claims 73,74 are objected to under 37 CFR 1 .75 as being a substantial duplicate of claims 20-28.

7. Claims 75,76 are objected to under 37 CFR 1 .75 as being a substantial duplicate of claims 30-38.

8. Claims 77-80 are objected to under 37 CFR 1 .75 as being a substantial duplicate of claims 38-49.

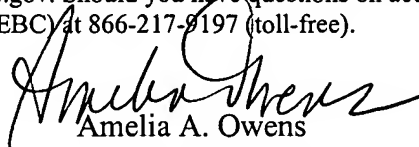
For above paragraphs 6-8, when two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP 7O6.03(k).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amelia A. Owens whose telephone number is 571-272-0690. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Amelia A. Owens
Primary Examiner
Art Unit 1625